

Environmental Protection Agency

§ 439.12

a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part, a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with a recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and measurement of a non-detect value for each regulated pollutant or its surrogate. Permits must specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

(b) Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged.

[68 FR 12271, Mar. 13, 2003]

§ 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

[63 FR 50425, Sept. 21, 1998]

§ 439.4 General limitation or standard for pH.

The pH must remain within the range 6.0 to 9.0 in any discharge subject to BPT, BCT or NSPS limitations or standards in this part.

[68 FR 12271, Mar. 13, 2003]

Subpart A—Fermentation Products

§ 439.10 Applicability.

This subpart applies to discharges of process wastewater resulting from the

manufacture of pharmaceutical products by fermentation.

[63 FR 50426, Sept. 21, 1998]

§ 439.11 Special definitions.

For the purpose of this subpart:

(a) *Fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.

(b) *Product* means pharmaceutical products derived from fermentation processes.

[68 FR 12271, Mar. 13, 2003]

§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The maximum monthly average limitation for BOD₅, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD₅ load of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily BOD₅ load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD₅ load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or